DEC 18 2013

K132186

510(k) Summary

Date:	December 13, 2013
510(k) owner's name:	Optomed Oy
Address:	Hallituskatu 13-17 D, 90100 Oulu, Finland
Contact person:	Jyri Leskelä, Quality Manager
Company phone:	+358 20 741 3380
Fax number:	+358 42 588 1187
Device name:	Trade name: Optomed Smartscope M5 digital camera with Optomed Smartscope EY4 optics module and Optomed Smartscope ES2 optics module Common/usual name: Ophthalmic camera Classification name: camera, ophthalmic, ac-powered (21 CFR 886.1120, Product code: HKI)
Predicate device:	Optomed Smartscope M5 with optics modules EY3 with ES1 (510(k) number: K110986, Product code: HKI)
Indications for Use:	Optomed Smartscope M5 digital camera with EY4 optics module is intended to capture digital images and video of the fundus of the human eye. Optomed Smartscope M5 with optics module ES2 is intended to capture images and video of the surface of the human eye and surrounding areas.

Device description, Intended use & Effectiveness:
Optomed Smartscope M5 digital camera with EY4 optics module is intended to capture digital images and video of the fundus of the human eye.

The device set for retinal imaging consists of:

- Camera handset M5
- Attachable ophthalmic lens EY4
- Eye cup for EY4
- Cradle for charging and image transfer
- Slit Lamp Adapter

Optomed Smartscope M5 with optics module ES2 is intended to capture images and video of the surface of the human eye and surrounding areas.

The device set for anterior ophthalmic imaging consists of:

- Camera handset M5
- Attachable anterior ophthalmic lens ES2
- Cradle for charging and image transfer

EY4 has an LED light source with visible white and infrared light. Also red light target LED's are used to eye position fixation during imaging. ES2 has an LED light source with white light and cobalt blue light. Image data is stored on the Flash memory card using 5 megapixel CMOS sensor and transferred to the PC by using USB connection. Device has rechargeable battery. Table 1 below includes a summary of the technical information used in the substantial equivalence comparison.

Table 1. Summary of the technical information.

Point of comparison	Optomed Smartscope M5 with EY4 and ES2	Optomed Smartscope M5 with EY3 and ES1
Indications for use	Optomed Smartscope M5 digital camera with EY4 optics module is intended to capture digital images and video of the fundus of the human eye. Optomed Smartscope M5 with optics module ES2 is intended to capture images and video of the surface of the human eye and surrounding areas.	Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area.
Usage	Prescription use	Prescription use
Use condition	Intended to use without mydriatic but can be used also with mydriatic	Intended to use without mydriatic but can be used also with mydriatic
Observation light source	Visible and infrared LED. EY4 LEDs: White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F ES2 LEDs: White : Osram Advanced Power Topled LW G6SP-EAFA-JKQL-1 Blue : Osram Advanced Power Topled LB G6SP-V2BB-35-1	Visible and infrared LED. EY3 LEDs: White: LWW5SM-KY-QK. NIR: SFH4232 (bin DA) ES1 LEDs: White : Osram Advanced Power Topled LW G6SP-EAFA-JKQL-1 Blue : Osram Advanced Power Topled LB G6SP-V2BB-35-1
Observation and display system	2.4" active matrix color TFT LCD	2.4" active matrix color TFT LCD
Photographing light source	Visible and infrared LED	Visible and infrared LED
Camera specification	Color CMOS camera maximum resolution 5Mp. ES2 uses maximum resolution. EY4 uses 1,77 Mp.	Color CMOS camera maximum resolution 5Mp. ES1 uses maximum resolution. EY3 uses 2,76 Mp.
Dioptre compensation (patient)	at least -20 D to +20 D	at least -20 D to +20 D
Picture angle	40 degrees	Over 40 degrees
Storage media	Flash memory card	Flash memory card
Image data format	JPEG, MPEG-1, MPEG-4	JPEG, MPEG-1, MPEG-4
Weight	Camera: 400g, EY4: 300g, ES2: 92g	Camera: 400g, EY3: 180g, ES1: 80g
Power consumption	Re-chargeable Ni-MH Battery 4.8V; Charging unit 44 VA	Re-chargeable Ni-MH Battery 4.8V; Charging unit 44 VA
Output terminals and data collection	USB (1.1) terminal (B-connector). Compatible with Windows® XP/VISTA/7.	USB (1.1) terminal (B-connector). Compatible with Windows® XP/VISTA/7.

Exposure parameters	"Exempt Group" (no risk) LED product according to EN 62471:2008 Group 2 instrument according to ISO 15004-2:2007	Class 1 LED according to IEC 60825-1:2001 Group 1 instrument according to ISO 15004-2:2007
Standards	IEC 60601-1:2005 (3rd edition) IEC 60601-1-2:2007 (3rd edition) EN 62471:2008 ISO 15004-2:2007	IEC 60601-1:1988+A1+A2 IEC 60601-1-2:2001+A1 IEC 60601-1-4:2000 EN (IEC) 60825-1:2001 +A1:2002+A2:2001 ISO 15004-2:2007

Technical Information was gathered by side-by-side comparison and labeling of the devices. Optomed Smartscope M5 with optics modules EY4 and ES2 and its predicate was also evaluated by Optomed development team and practicing physicians throughout the product development.

Following laboratory bench tests demonstrate Optical radiation safety of the Optomed Smartscope M5 with EY4 and ES2:

1. Optical radiation hazards as defined by standard ISO 15004-2, Ophthalmic instruments -- Fundamental requirements and test methods -- Part 2: Light hazard protection, First edition 2007-02-15.
2. Maximum photometric luminance
3. the optical radiation hazards as defined by ISO 15004 for:
   (i) ultraviolet and infrared radiation, and
   (ii) visible light and near IR radiation (blue-light weighted radiance and aphakic weighted radiance).

Optomed Smartscope M5 with optics modules EY4 and ES2 is classified as Class 2 instrument according to the international standard ISO 15004-2:2007.

Optomed Smartscope EY3 eye optics is a predecessor of EY4 eye optics. The modifications in M5 camera with EY4 optics compared to M5 camera with EY3 optics are:

- Resolution is improved to meet the requirements of ISO10940 (Fundus camera standard)
- Target LED's for eye position fixation during imaging
  - 9 pcs of LEDs at different viewing angles
  - Allows stabilizing the eye of the patient for a specific direction.

Optomed Smartscope ES1 eye optics is a predecessor of ES2 eye optics. The modifications in M5 camera with ES2 optics compared to M5 camera with ES1 optics are:

- Illumination concept is improved
  - New diffuser structure to improve image quality
  - Separate baffle is included in the illumination path to block excess reflections of stray light from the sides of the module
  - to enhance image contrast
  - to allow shorter camera integration times to reduce motion blur

Based on the comparison and supportive information, the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Optomed Oy
% Mr. Jyri Leskelä
Quality Manager
Hallituskatu 13-17
FI 90100, Oulu
Finland

Re: K132186
Trade/Device Name: Optomed Smartscope M5 digital camera with Optomed Smartscope EY4 optics module and Optomed Smartscope ES2 optics module
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 4, 2013
Received: November 6, 2013

Dear Mr. Leskelä:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, and Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132186

Device Name: Optomed Smartscope M5 digital camera, Optomed Smartscope EY4 optics module, Optomed Smartscope ES2 optics module

Indications for Use:
Optomed Smartscope M5 digital camera with EY4 optics module is intended to capture digital images and video of the fundus of the human eye.

Optomed Smartscope M5 with optics module ES2 is intended to capture images and video of the surface of the human eye and surrounding areas.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
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